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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/083,793	05/22/1998	BRIAN R. MURPHY	17634-000320	4558

7590 02/21/2003

Jack Spiegel
Woodcock Washburn LLP
One Liberty Place
46th Floor
Philadelphia, PA 19103

EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/083,793

Applicant(s)

MURPHY ET AL.

Examiner

Stacy S Brown

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-94 and 96-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-94 and 96-143 is/are rejected.
- 7) ☒ Claim(s) 90, 142 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 1998 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, examiner Stacy Brown.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2002 has been entered. Claims 1-94 and 96-143 are pending and examined.

3. The original claims submitted May 22, 1998 are missing from the PTO's file wrapper. Attempts to locate the original claims have not been successful. Applicants are requested to provide a copy of the original claims. The Office regrets any inconvenience to Applicant.

4. Applicant's response filed August 26, 2002, pages 4-6, contain references to the previous Examiner's comments contained in previous Office Actions. Applicants requested clarification regarding 1) procedural considerations, 2) status of evidence in record and 3) applicant's burden of proof in rebutting the alleged anticipatory reference. In a personal interview on November 22, 2002, Attorney Jeffrey King, Applicants Brian Murphy and Peter Collins, Primary examiner Park and examiner Brown discussed the outstanding rejections in this application (Paper No. 30).

Response to Amendment

5. The rejection of claim 111 under 35 U.S.C. 112, second paragraph is withdrawn in view of Applicant's amendments. The rejection of claims 91 and 92 under 35 U.S.C. 102(b) as anticipated by Dimock *et al* (*J. Virology*, 1993) is withdrawn in view of Applicant's amendments.

6. The rejection of claims 15, 16, 30, 31, 36, 37, 39, 65-69, 71, 72, 78, 81, 82, 105, 106, 109-111, 113, 114, 117, 127, 128, 130, 131, 133, 135, 138 and 139 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's declaration (submitted September 3, 2002) relating to the deposited material.

7. The following rejections are withdrawn in view of the Murphy Declaration submitted August 26, 2002:

- The rejection of claims 1-94 and 96-143 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn (paragraph 9 of the Murphy Declaration).
- The rejection of claims 1-4, 6, 7, 10-17, 20, 21, 26, 27, 30, 33-40, 43, 44, 47-49, 52, 54, 56, 57, 59, 61-85, 88-91, 93, 94, 96-116, 118 and 120-143 under 35 U.S.C. 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Belshe *et al* (5,869,036), is withdrawn.
- The rejection of claims 51 and 53 under 35 U.S.C. 103(a) as obvious over Belshe *et al* is withdrawn.

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- The rejection of claims 18, 19, 28 and 29 under 35 U.S.C. 102(e) as anticipated by Belshe *et al*, or in the alternative, under 35 U.S.C. 103(a) as obvious over Belshe *et al* in view of Stokes *et al* (*Virus Research*, 1993) is withdrawn.
- The rejection of claims 22-25, 31, 32, 42, 60, 117 and 119 under 35 U.S.C. 103(a) as obvious over Belshe *et al* in view of Conzelmann (*J. Gen. Vir.*, 1996) is withdrawn.

8. The Murphy Declaration, submitted August 26, 2002, and Applicant's arguments have been carefully considered. The rejections hinging on the enablement/non-enablement of Belshe (5,869,036) are addressed in the Declaration. Belshe fails to show any working examples of recovery of recombinant PIV from cDNA. Dr. Murphy attributes this failure to many deficiencies in Belshe. A notable deficiency is that Belshe fails to provide an accurate sequence of a wild type PIV. Further, Belshe's PIV3 sequence was taken from published sequences of others, which were found to contain errors and lacked identification of many major attenuating mutations. Applicants have corrected the errors in the sequence of the wild type PIV and identified major attenuating mutations. Applicants have provided exact lengths of a full length cDNA for PIV3 that take into account the "rule of six", not disclosed by Belshe as a critical factor in recovery of authentic copies of virus without random mutations. In view of these deficiencies, one of skill in the art would not have expected to recover recombinant PIV according to Belshe's teachings.

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Claim Objections

9. Claims 90 and 142 are objected to because of the following informalities: Claim 142, “genes of HPIV3 to for said infectious, chimeric particle” is unclear. In claim 90, line 1, “infectious” is misspelled.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 90, 115 and 116 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition that *induces an immune response* against PIV and/or RSV, does not reasonably provide enablement for *protective immunity* against PIV and/or RSV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. While there is some ambiguity regarding the meaning of claims 47, 90 and 115 (see rejection under 35 U.S.C. 112, second paragraph), the claims are interpreted in their broadest sense.

The nature of the invention in claims 47, 90, 115 and 116 is a polypeptide or polynucleotide encoding a polypeptide that confers protective immunity against PIV and/or RSV. PIV/RSV vaccines provide protective immunity resulting in non-infection when challenged with PIV and/or RSV. The state of the prior art is described in Applicant's specification, pages 2-3, which disclose that several vaccine *candidates* have been studied for

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PIV. However, the protection referred to by Karron (reference AZ in the IDS) is limited to infants and children using bovine PIV3. As for RSV, the state of the prior art shows that RSV antigens have been tested for immunogenicity, but only antibodies (Synagis™) have been successful in reducing viral load. Applicant's specification has provided examples of protection in hamsters (pages 122-124) which would lead one of skill in the art to further experimentation and testing of the vaccine candidates for use in humans (page 18, lines 26-29).

This rejection can be overcome by clarifying Applicant's definition and scope of protective immunity intended for the claims, or amending the claim language to "inducing an immune response".

Claim Rejections - 35 USC § 112

11. Claims 10-47, 90, 115, 118-128, 133-134 and 142-143 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 10 contains improper Markush language.
- Claim 11, it is unclear which polynucleotide is being referred to in the last "said polynucleotide" in line 5.
- Claims 47, 90, 115 and 116, "capable of" is unclear because it is not known whether or not the pathogen actually elicits a protective immune response.
- Claims 47, 90 and 115, it is unclear which element is eliciting a protective immune response. Is it the particle as a whole, the PIV portion, the non-PIV portion, or the pathogen?

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- Claim 118, "immunogenically effective amount" is unclear. How does one measure immunogenic effectiveness? Is it simply inducing an immune response?
- Claim 124, there is no antecedent basis for "said infectious, chimeric PIV particle".

Double Patenting

12. Claims 1-94 and 96-143 remain provisionally rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over:

- Claims 1-6, 8-45, 47-50 of copending Application 09/458,813,
- Claims 1-58 of copending Application 09/459,062, and
- Claims 1-94 and 96-128 of copending Application 09/424,628.

Claims 1, 2, 5-10, 33-42, 73, 74, 76-80, 83, 88, 89, 97-99, 107-111, 122, 123 and 141 remain provisionally rejected for reasons of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-83 of copending Application 09/586,479.

Applicant has indicated that these provisional obviousness-type double patenting rejections will be addressed later.

Conclusion

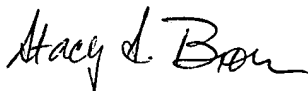
13. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number

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for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
January 24, 2003



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER